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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,911	12/18/2001	Kit Yeng Lim	SBI-100	4817

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EXAMINER

RAMANA, ANURADHA

ART UNIT PAPER NUMBER

3733

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,911	LIM ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-17, 19-28, 30-33, 35 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-17, 19-28, 30-33, 35 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 12, 2005 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10-17, 19-28, 30-33, 35 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Upon careful review of Applicants' disclosure, it is the Examiner's position that the limitation, "without engaging the endplates" and "thread does not engage a vertebra" is new matter. Applicants' disclosure does not specify that Applicants' plug contacts only intact annular tissue surrounding defect 20. Figure 3 shows an annular defect 20 that extends across the annulus. If plug 30 is inserted using a screw driver plug 30 could contact the upper and lower vertebral endplates (see page 9, lines 29-34 of Applicants' specification).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 6, 10-11 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Boyer, II et al. (US 6,767,369).

Boyer, II et al. disclose a plug 280 for filling vacancies or defects in bone tissue having an external thread 286 and apertures 284; the plug being formed using resorbable or “biodegradable material” and filled with bone growth materials or “compounds” (Figs 1A-1J, 3N, col. 3, lines 66-67, col. 4, lines 1-56, col. 8, lines 31-59, col. 9, lines 8-65, col. 10, lines 47-67, col. 11, lines 1-67 and col. 12, lines 1-45). Boyer, II et al. further disclose that a cap may be coupled to the sleeve (col. 13, lines 41-45 and col. 19, lines 34-56).

With regard to the thread being, “configured to engage annular tissue without engaging the endplates,” it has been held that the recitation that an element being configured or adapted to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. In the instant case, depending on the size of the annular defect the thread 286 can engage annular tissue without engaging the vertebral endplates.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyer, II et al. (US 6,767,369) in view of Michelson (US 5,593,409).

Boyer, II et al. disclose all elements of the claimed invention except for a cap with a slot for mating with a tool.

Michelson teaches a removable cap for an implant with a hex slot 734 for engaging a hex tool (Fig. 41 and col. 15, lines 3-11).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a cap with a slot, as taught by Michelson, in the Boyer, II et al. plug, so that the plug may be inserted or rotated with a driver or tool.

Claims 4-5, 7-8, 12, 14, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyer, II et al. (US 6,767,369) in view of Boyce et al. (US 6,294,187).

Regarding claims 4, 5, 14 and 15, Boyer, II et al. disclose all elements of the claimed invention except for resorbable materials such as biodegradable polymers.

Regarding claims 7, 8, 12 and 17, Boyer, II et al. do not disclose specific types of bone growth materials.

Boyce et al. teach the use of biodegradable polymers such as polylactic-co-glycolic acid, polycaprolactone, polycyanoacrylates etc. to make an implant used for bone repair (col. 8, lines 23-40).

Boyce et al. also teach the use of bioactive substances such as antibiotics, living cells, peptides, growth factors such as TGF-beta, bone morphogenetic proteins (BMPs), angiogenic agents etc. in a bone repair device or implant to accelerate the ingrowth of new bone tissue into the implant (col. 9, lines 31-67).

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Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have made the Boyer, II et al. implant of a biodegradable polymer, as taught by Boyce et al. to make the Boyer, II et al. implant biodegradable. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the bioactive substances taught by Boyce et al. in the Boyer, II et al. implant to promote bone growth when the implant of the combination of Boyce et al. and Boyer, II et al. is used for bone repair.

Response to Arguments

Applicants did not file any arguments in the response submitted on December 12, 2005. Since Applicants did not request that the reply previously filed on November 15, 2005 be considered, the Examiner has not provided a response to the arguments presented in the response submitted on November 15, 2005 in this action.

Conclusion

Non application of prior art indicates subject matter not disclosed, taught or suggested by prior art.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR

January 8, 2006

Amudha Ramana
AU 3733